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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/632,806	08/04/2000	Lise Thibodeau	045636-5039	2513

9629 7390 10/18/2002

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EXAMINER

PARKIN, JEFFREY S

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 10/18/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/632,806

Applicant(s)

THIBODEAU ET AL.

Examiner

Jeffrey S. Parkin, Ph.D.

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 03 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-20 is/are pending in the application.
- 4a) Of the above claim(s) 6-14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-20 is/are rejected.
- 7) ☒ Claim(s) 15-20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

Detailed Office Action***Status of the Claims***

1. Applicants' election with traverse of Group III (claims 15-20) in paper no. 8 is acknowledged. However, since applicants failed to distinctly and specifically point out the purported errors in the restriction requirement, the election has been treated as an election without traverse (refer to M.P.E.P. § 818.03(a)). Claims 1-14 are withdrawn from further consideration by the examiner, pursuant to 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention.

Claim Objections

2. Claims 15-20 are objected to because of the following informalities: applicants are reminded of the restriction requirement set forth in paper no. 7. The elected claims are currently directed toward a vaccine composition comprising a recombinant HIV-1 envelope protein with a modified V3 loop. The claims should be amended to reflect this election. Appropriate correction is required.

35 U.S.C. § 112, Second Paragraph

3. Claims 15-20 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims, which are directed toward a vaccine composition, reference a product employed in another set of claims which are directed toward a viral inhibitory method. Thus, the salient characteristics of the claimed invention are not readily manifest. Appropriate correction is required.

35 U.S.C. § 103(a)

4. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

5 (a) A patent may not be obtained though the invention is not
identically disclosed or described as set forth in section 102 of
this title, if the differences between the subject matter sought to
be patented and the prior art are such that the subject matter as
a whole would have been obvious at the time the invention was made
10 to a person having ordinary skill in the art to which said subject
matter pertains. Patentability shall not be negated by the manner
in which the invention was made.

15 Subject matter developed by another person, which qualifies as
prior art only under subsection (f) or (g) of section 102 of this
title, shall not preclude patentability under this section where the
subject matter and the claimed invention were, at the time the
invention was made, owned by the same person or subject to an
obligation of assignment to the same person.

20 5. This application currently names joint inventors. In
considering patentability of the claims under 35 U.S.C. § 103(a),
the examiner presumes that the subject matter of the various claims
was commonly owned at the time any inventions covered therein were
made absent any evidence to the contrary. Applicant is advised of
25 the obligation under 37 C.F.R. § 1.56 to point out the inventor and
invention dates of each claim that was not commonly owned at the
time a later invention was made in order for the examiner to
consider the applicability of 35 U.S.C. § 103(c) and potential 35
U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

30 6. Claims 15-20 are rejected under 35 U.S.C. § 103(a) as being
unpatentable over Haigwood et al. (1998) in view of Cates et al.
(2000). Haigwood and colleagues (1998) provide HIV-1 envelope
mteins with various portions of the V3 loop deleted. These
35 recombinant envelopes were highly immunogenic. Cates and
associates (2000) provide immunogenic compositions comprising a
viral envelope glycoprotein and various art-recognized adjuvants
(e.g., aluminum hydroxide, liposomes, etc.). Therefore, it would
have been *prima facie* obvious to one having ordinary skill in the

art at the time the invention was made to prepare a vaccine composition comprising a modified HIV-1 envelope mutein as taught by Haigwood et al. (1998) and an art-recognized adjuvant as provided by Cates et al. (2000). This would result in the production of a highly immunogenic envelope composition that will direct the immune response away from the V3 loop and towards more immunologically important epitopes.

Correspondence

7. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242 or (703) 305-3014. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 308-4426. Applicants are encouraged to notify the Examiner prior to the submission of such documents to facilitate their expeditious processing and entry.

8. Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227. The examiner can normally be reached Monday through Thursday from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, James Housel or Laurie Scheiner, can be reached at (703) 308-4027 or (703) 308-1122, respectively. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Respectfully,

Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

30 September, 2002